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13. ABSTRACT *(Maximum 200 Words)*

The Institute for Laboratory Animal Research (ILAR) is a component of the Division on Earth and Life Studies (DELS) at The National Academies. The Department of the Army has provided partial support for ILAR for many years to enable to ILAR fulfill its mission. ILAR was founded in 1952 and is a national and international leader in developing guidelines for animal care, breeding, and use; descriptions of animal models for human diseases and physiological processes; and reports on specific issues of humane care and use of laboratory animals. ILAR's mission is to help improve the availability, quality, care, and humane and scientifically valid use of laboratory animals and to disseminate its reports and other relevant information to the biomedical and laboratory animal science communities. ILAR accomplishes its goals through its core program, which is carried out by the staff, and its special-project program, which is carried out by NRC-appointed committees with staff assistance. A 15-member Council composed of experts in laboratory animal medicine, zoology, genetics, medicine, ethics, and related biomedical sciences directs both programs. The Army funds partially support general office operations, the Animal Models and Genetic Stocks Information Program, publication of *ILAR Journal*, and work of the Council.

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INTRODUCTION

For many years the Army has provided partial core support to the Institute for Laboratory Animal Research (ILAR), a component of the National Research Council (NRC). Formerly contained within the Commission on Life Sciences, ILAR is now part of a larger division of the NRC, called the Division on Earth and Life Studies. The NRC is the operating arm of the National Academy of Sciences, a private, nonprofit organization that was created in 1863 by congressional charter to serve as an official advisor to the federal government on questions of science and technology.

Founded in 1952, ILAR is both a national and international leader in developing guidelines for animal care, breeding, and use; descriptions of animal models for human diseases and physiological processes; and reports on specific issues of scientific and humane use of laboratory animals. ILAR disseminates this information to the biomedical and laboratory animal science communities by wide distribution of its reports as well as through presentations and exhibits at national meetings. These guidelines from the National Academy of Sciences serve as important indications to members of the U.S. Congress and other government officials, the press, and the public of the high quality of care provided to laboratory animals. ILAR's mission is to help improve the availability, quality, care, and humane and scientifically valid use of laboratory animals.

Recognized experts in fields appropriate to the required tasks carry out ILAR's studies, like all those of the NRC. These experts serve on a volunteer basis, without compensation. As a part of the NRC, ILAR has access to this country's most knowledgeable and distinguished laboratory animal and biomedical scientists, who provide objective counsel on laboratory animal issues. Many of the experts used by ILAR are also members of the National Academy of Sciences or the Institute of Medicine. In some cases, ILAR utilizes scientists from other countries.

Independent NRC-appointed experts in the subject area extensively review reports of NRC studies before they are released. They are prepared in sufficient quantity to ensure distribution to the sponsor, experts, and other relevant parties in accordance with Academy policy. Reports are usually made available to the public without restriction.

ILAR'S GOALS

Since its founding, ILAR has provided guidance and information on laboratory animal matters to the federal government, the biomedical and laboratory animal science communities, and the public. In keeping with its mission, ILAR continually seeks to strengthen and refine its existing programs and to initiate new programs that will assist government officials; scientists who use animals in research, testing, and education; and the institutional animal care and use committees that monitor animal use. ILAR's goals are as follows:

- to provide a forum within the National Academy of Sciences for the Department of Defense to discuss issues and develop guidance for laboratory animal-related matters;
- to continue to serve on behalf of biomedical science and education as an authoritative voice within the U.S., and on behalf of the U.S. scientists internationally;
- to promote humane and appropriate care and use of laboratory animals;
- to provide scientific guidance on laboratory animal-related issues to agencies of the federal government and others on request;
- to provide information on laboratory animal matters to government officials, laboratory animal and other biomedical scientists, institutional animal care and use committees, and the public;
- to promote the use of standardized nomenclature for accurately defining and identifying genetic stocks of animals;
- to assist developing countries in attaining quality laboratory animal science programs through dissemination of information including the translation of ILAR reports;
- to promote cost-effective ways to preserve valuable animal models;
- to sponsor workshops in areas of importance the laboratory animal community; and
- to increase access to information about appropriate biological models and methods through ILAR's home page, databases, publications, and resources of the ILAR Associates program, including the quarterly *ILAR Journal.*

Accomplishing the Goals

ILAR accomplishes its goals through its core program, which is carried out by the staff, and its special-project program. The number of studies and size of the staff are dependent on the number of special projects and available funding. Both programs are directed by a 15-member ILAR Council composed of experts in laboratory animal medicine, virology, zoology, genetics, medicine, ethics, and related biomedical sciences.

THE CORE PROGRAM

ILAR Council

The ILAR Council (see addenda for roster) serves four principal functions: 1) to provide program direction and strategic planning; 2) to oversee the information and outreach programs, which consist of the Animal Models and Genetic Stocks Information Program, the ILAR web site, and the quarterly *ILAR Journal;* 3) to oversee special projects; and 4) to direct ILAR's international programs and its participation as the U.S. national member in the International Council of Laboratory Animal Sciences (ICLAS). The international program is discussed in the Special Projects section below. Periodically, the Council meets with other scientists and funding agency administrators to discuss areas in which ILAR might prove useful. It then uses these discussions in strategic planning. The Council occasionally employs core funds to undertake specific, NRC-approved projects itself.

Staff

ILAR is staffed by a director, a managing editor of the *ILAR Journal*, a project assistant who maintains the web page and various databases, an administrative assistant and secretary to the director, and a project director. Under the special projects program, staff works closely with experts to engage in studies, develops working papers, assists in the production of cohesive reports, and conducts literature reviews.

Animal Models and Genetic Stocks Information Program

Some of the most critical information needed by Department of Defense scientists is often the most difficult to obtain, including information on the most appropriate model for the proposed research and, if the model is an animal, to find sources of the model and information on appropriate care. As author of the *Guide for the Care and Use of Laboratory Animals*, ILAR is in a position to assist investigators and Institutional Animal Care and Use Committees (IACUCs) in interpreting guidelines for the humane care and use of animals and fulfilling requirements of the Animal Welfare Act and PHS policy regarding reduction of pain and distress and identification of alternative methodologies. For more than 40 years, ILAR has conducted a program to provide such information. That program, called the Animal Models and Genetic Stocks Information Program, offers assistance in locating sources of animals, selecting appropriate animal models, using standardized nomenclature, and understanding the importance of the use of animals in biomedical and behavioral research and testing. It includes two databases: one (called Animals for Research, AFR) contains information about commercially available and investigator-held colonies of animals for research; the other is a registry of codes used with standardized nomenclature of rodents and rabbits to identify institutions that maintain breeding colonies. The databases have been incorporated into ILAR's web pages and are available to investigators worldwide. Under the guidance of experts on Council and a part-time new staff person with expertise in web design, ILAR has undertaken a major revision of the AFR database that has made it more useful and current, and has enabled it to be maintained more easily. In fact, in the last year, the entire web site has been reorganized and made more user-friendly with the addition of a search engine that facilitates the quest for information.

ILAR Journal

ILAR Journal, a quarterly, peer-reviewed publication, provides thoughtful and timely information for all those who use, care for, and oversee the use of laboratory animals. The readership of *ILAR Journal* includes more than 3,500 investigators in biomedical and related research, institutional officials for research, veterinarians, and members of animal care and use committees. The *ILAR Journal* Editorial Board, of the ILAR Council, plans each issue around a chosen theme and carefully solicits authors who can best present a balanced view of the topic. Each article undergoes a rigorous peer review.

ILAR Journal, under the capable leadership of managing editor Susan Vaupel and the Editorial Board, continues to be timely in its publication. During the last year, issues have been

published on the following themes: Impact of Noninvasive Technology on Animal Research (1), Fish Models in Biomedical Research (2), Implications of Human-Animal Interactions and Bonds in the Laboratory (3) and Mouse Models of Human Diseases (4). Themes of forthcoming issues include: Advanced Physiological Monitoring in Laboratory Animals, Principles of Experimental Design in Biomedical Research, Occupational Health and Safety in Biomedical Research and Animal Models of Stroke and Rehabilitation.

ILAR Associates Program

In an effort to increase ILAR's information and resources and to better leverage funding from core and project sponsors, ILAR initiated an Associates program in 1997. Individuals and institutions that subscribe to the Associates program help defray the cost of publishing the *Journal*. ILAR Associates receive the *ILAR Journal* (number of copies varies with level of Associate membership) and a 20% discount on all ILAR and other National Academy Press publications. As do ILAR's core sponsors, the Associates arguably represent the best of US biomedical and laboratory animal scientists and serve as an important audience to receive, critique, and provide guidance to ILAR's programs. ILAR's core sponsors are valuable members of the Associates program.

SPECIAL PROJECTS

Projects are developed in response to specific requests from government agencies and private organizations or on the initiative of staff or of ILAR Council. Although contracts and grants from federal agencies, foundations, and private organizations support these projects, they are never completely separate from the core program because the Council is involved during each step of the process. This sponsorship provided by this grant is recognized in each published ILAR report. The Council reviews each project extensively before it is undertaken, examines the qualifications of experts, oversees the progress of the project to ensure that it is accomplished in a timely manner, and reviews and signs off on each report as a part of the NRC review process. In addition, ILAR reports are frequently published as special inserts of the core-supported *ILAR Journal*. The following are examples of recently completed projects, or projects that are under way or which will begin when funding has been received.

ICLAS and International Activities

ILAR has had a long history of interest in international laboratory animal science. Historically, this interest has sought to assist young investigators in developing countries through dissemination of reports (some translated into foreign languages to increase their usefulness) and participation in international meetings that support young investigators. In 1988, ILAR became the U.S. national member of the International Council for Laboratory Animal Science (ICLAS), with support from member agencies (including USAMRDC) of the Interagency Research Animal Committee (IRAC). This membership affords a conduit for U.S. investigators to develop and conduct an active international program in laboratory animal science. One goal of the U.S. membership in ICLAS was to streamline ICLAS management and programs to better represent U.S. scientists in the

international community. In 1995, that goal came to fruition through the election of former ILAR Council chairman (Steven Pakes) as Secretary General of the ICLAS General Assembly. Dr. Pakes is currently the president of ICLAS and continually works closely with ILAR. He is an annual guest of ILAR Council to discuss ICLAS and other international issues.

The goals of ILAR's international activities center on the following:

- Facilitating the impact of NAFTA for the benefit of trade affecting scientific exchange
- Developing a database of contacts (scientists, government officials, and trade organizations) in Mexico and Canada
- Distributing NRC reports to appropriate scientific audiences
- Translating Reports

Perhaps the most longstanding international activity is our effort to have our seminal publication *Guide for the Care and Use of Laboratory Animals* (the *Guide*) (5) translated into as many languages as possible. The *Guide* is used as the standard for laboratory animal care by the Public Health Service in the U.S. and by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International in their certification of animal facilities throughout the world. To date, the *Guide* has been translated into French, Spanish, Portuguese, Thai, Japanese, Chinese, Taiwanese, Korean, Arabic, and Russian. The use of the *Guide* internationally by scientists and laboratory animal personnel further supports ILAR's effort to achieve animal care and use policies that will facilitate international scientific exchange of biologics and products. ILAR has now begun to track the international distribution of its other publications in order to determine which of these, if any, should be translated. Reports likely to have a high level of international interest include *Occupational Health and Safety in the Care and Use of Research Animals* (6) and *The Psychological Well-Being of Nonhuman Primates* (7).

ILAR has sponsored international meetings to promote dialogue and harmonization on the care and handling of laboratory animals. Annual meetings between U.S. and Japanese scientists have occurred for twenty years, and ILAR assumed the sponsorship of these meetings from the NIH. In the last year, the International Committee of ILAR Council proposed that the scope of these meetings change to include a broader spectrum of countries in the discussion. To this end, the next international workshop is titled *International Perspectives – The Future of Nonhuman Primate Resources* and will be held on April 17-19, 2002 in Washington, DC. Speakers from six continents will make presentations and discuss common issues regarding nonhuman primate resources for biomedical research. In particular, they will address the shortage of rhesus macaques for AIDS research. The outcome of this workshop will be a proceedings. By promoting the harmonization of methods for the care and use of animals, ILAR hopes to improve the quality of information exchange among countries, with the goal of ultimately reducing the number of animals used, and to provide guidance in the field of laboratory animal science to scientists in developing countries.

In 1999, ILAR was granted observer status to the Council of Europe in the preparation of guidelines for the protection of live animals used for experimental and other scientific purposes. The goal of the Council of Europe is to harmonize guidelines throughout Europe, and it is

desirable to have these guidelines harmonized with regulations and guidelines in the U.S. Since the *Guide* provides the basis for many of the current U.S. guidelines, it is useful and efficient for ILAR to be an observer to this process and have the opportunity to comment.

PROJECTS COMPLETED DURING THE LAST FUNDING PERIOD

Workshops on Regulatory Issues in Laboratory Animal Care and Use

The second workshop in this series was held on May 21-22, 2001, and was titled "Regulation of Laboratory Animals – Is It Time to Rethink Policy?" The purpose of this workshop was to determine whether ILAR should conduct a study to make recommendations on consolidating regulations of laboratory animals. Specifically, ILAR would aim to eliminate duplications while ensuring that all animals are covered adequately, making the regulatory process more efficient while providing for the best care of all laboratory animals. The speakers addressed current regulations for laboratory animals as well as proposed new regulations under the Animal Welfare Act, and highlighted current practices for laboratory animal care including instances of duplication of oversight as well as institutions not covered under any regulation. Other presentations focused on possible alternative oversight schemes, animal welfare considerations, and legislative issues. The workshop closed with a panel discussion. Proceedings of the workshop could not be published because it was conducted though Program Initiation Funds provided by the National Academies. The purpose of the workshop was to pose the question of ILAR performing a study in the area. While some speakers agreed with the concept of ILAR doing a study, there was not a clear mandate to do so. ILAR Council decided that ILAR should wait to determine the course of action with regard to inclusion of rats, mice and birds, and then proceed to either do a study to advise USDA on the impact of such regulation, or to do a more broad-based study on streamlining the current regulatory scheme.

PROJECTS IN PROGRESS

Occupational Health and Safety in Care of Non-human Primates

A committee of experts has met three times in the last year to prepare the report which will identify the hazards associated with non-human primates in research, education, and testing; assess the degree of risk of these hazards; and suggest options for managing the risks including engineering controls, administrative procedures, personal protective equipment, and worker training. The report is in its final stages of preparation before submission for review and will be published by June 2002. The roster of committee members is included in the Appendix.

Revision of the 1991 publication for students: *Science, Medicine and Animals*

The revision will address animal use in scientific and medical research. This report, which is in the final stages of completion, will provide an objective assessment of the scientific issues associated with the use of animals in research; examine historic impacts in human and animal science and medicine attributable to the use of animals in research; explore alternatives to the use of animals; define current legal and regulatory aspects of laboratory animal use; and present examples of appropriate, responsible, and contemporary approaches to the use of animals

in research. ILAR is consulting with designers to provide graphics and other visuals for the report to make it attractive to students and other target audiences.

Guidelines for Use of Animals in Neuroscience and Behavioral Research

An ad hoc committee has been appointed to prepare a document that will identify common research themes in neuroscience and behavioral research, describe methods for recognizing and minimizing any negative impact the research might have on health and welfare of the animals, and discuss the innovations and limitations of each method. A new staff officer, Dr. Jennifer Obernier, has been hired to direct this project and has already conducted one committee meeting in February 2002. The second committee meeting will be held in May. The roster of committee members is included in the Appendix.

PROSPECTIVE ACTIVITIES (APPROVED PROJECTS IN NEED OF FUNDING)

Laboratory Animal Housing

The 1978 ILAR report titled *Laboratory Animal Housing* will be updated using modern technical criteria for animal research facility design including performance criteria, description of the animal environment, requirements for hazardous agent containment, and cost-effectiveness of various designs for new construction as well as renovation. A grant application to NIH to support this project has recently been reviewed.

Increasing Veterinary Involvement in Biomedical Research

A study will be done in which an appointed committee will address issues surrounding recruitment and training of veterinarians in two areas of critical need: comparative medicine/pathology and clinical management of laboratory animal facilities.

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